

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
MIDLAND / ODESSA DIVISION**

STATE OF TEXAS, AND MAYO)	
PHARMACY INC., A NORTH DAKOTA)	
CORPORATION.,)	No. 7:23-cv-00022-DC
<i>Plaintiffs;</i>)	
)	
v.)	
)	
XAVIER BECERRA, in his official capacity)	
as Secretary of Health and Human Services;)	
UNITED STATES DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES;)	
UNITED STATES DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES OFFICE)		
FOR CIVIL RIGHTS,)	
<i>Defendants.</i>)	
)	

**DEFENDANTS' RESPONSE TO PLAINTIFFS' OBJECTIONS TO DEFENDANTS'
NOTICE OF ADMINISTRATIVE RECORD**

Defendants hereby respond to Plaintiffs' Objections to Defendants' Notice of Administrative Record, Doc. 56 ("Objections"). With limited exceptions discussed below, the materials listed in plaintiffs' Objections are not part of the administrative record, and plaintiffs have not met their burden to establish otherwise. Plaintiffs' Objections ignore the governing legal standards. The Administrative Procedure Act (APA) authorizes review of "final agency action." 5 U.S.C. § 704. For a reviewable final agency action, "[t]he complete administrative record consists of all documents and materials directly or indirectly considered by the agency." *Fath v. Texas Dep't of Transportation*, No. 1:16-cv-234, 2017 WL 11633326, at *1 (W.D. Tex. Mar. 17, 2017) (quoting *Bar MK Ranches v. Yuettter*, 994 F.2d 735, 739 (10th Cir. 1993)).¹ An agency's "designation of the Administrative Record . . . is entitled to a

¹ Plaintiffs cite a case applying the distinct standard for the scope of an administrative record in

presumption of administrative regularity.” *Id.* (quoting *Yuetter*, 994 F.2d at 739–40). To “rebut the presumption,” a plaintiff must present “clear evidence” that documents “were improperly omitted from the designated Administrative Record.” *Id.*

Defendants acknowledge that in issuing the Superseded Guidance, they considered the Guidance on Nondiscrimination Protections under the Church Amendments, <https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html>, *see* Objections ¶ 1.c.² Defendants further acknowledge that in issuing the Revised Guidance, they considered the notice announcing the closure of investigations of CVS and Walgreens, *see* Objections ¶ 3.c. Accordingly, defendants included these documents in the Supplemental Administrative Record, Doc. 58-3, filed today.

The remaining documents identified in plaintiffs’ Objections properly were not included in the administrative record. Plaintiffs fail to provide any evidence, let alone clear evidence, that the documents listed in the Objections were improperly omitted from the administrative record. The Supplemental Certification of the Administrative Record, Doc. 58-2, also filed today, shows that OCR did not consider any of these documents in issuing either the Superseded Guidance or Revised

challenges to a benefits plan’s denial of benefits under the Employee Retirement Income Security Act of 1974 (ERISA). Doc. 56 at 6–7 (citing *DaVita Inc. v. Scot Indus. Inc.*, No. 17-cv-480, 2019 WL 13210623, at *2 (E.D. Tex. Feb. 13, 2019)). Under the ERISA standard, which is not applicable to this case, “relevant information made available to the administrator prior to the complainant’s filing of a lawsuit” is part of the administrative record, regardless of whether the plan administrator considered the information in making a decision. *DaVita*, 2019 WL 13210623, at *2 (quoting *Vega v. Nat'l Life Ins. Servs., Inc.*, 188 F.3d 287, 300 (5th Cir. 1999)). By contrast, in APA cases like the case at bar, “matters not considered by the agency are generally outside the record” and “are legally irrelevant.” *City of Dallas, Tex. v. Hall*, No. 3:07-cv-60, 2007 WL 3257188, at *4 (N.D. Tex. Oct. 29, 2007).

² In issuing the Superseded Guidance, defendants also considered Executive Order 14,076, *see* Objections ¶ 1.a, and the Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*, Objections ¶ 1.b. Consistent with typical agency practice in submitting administrative records, defendants did not include readily available legal authorities, such as Supreme Court decisions, executive orders, and statutes. In the interest of avoiding unnecessary controversy, defendants have no objection to deeming the Executive Order 14,076 and the *Dobbs* decision to be part of the administrative record.

Guidance. Plaintiffs have not overcome the “presumption of administrative regularity” to which that certification is entitled. *Fath*, 2017 WL 11633326, at *1.

For most of the documents listed in the Objections, the sole justification provided by plaintiffs for including them in the administrative record is that the documents either were cited in the press release announcing the pharmacy guidance or were cited in materials cited in that press release. *See, e.g.*, Objections ¶ 1.a (document was “cited in the original guidance press announcement”). But the press release summarizes the pharmacy guidance and then lists a number of other actions that HHS had recently taken. *See* ECF No. 14-1. The fact that a document was cited in the discussion of other HHS actions listed in the press release does not show that OCR considered the document in issuing the Superseded Guidance or the Revised Guidance, and the supplemental certification confirms that those documents were not considered.

To the extent plaintiffs object that defendants should have produced an administrative record for the press release, that argument fails because the press release is not a final agency action for which defendants are required to produce an administrative record. A final agency action must (1) represent “the consummation of the agency’s decisionmaking process,” and (2) conclusively determine legal “rights or obligations.” *Bennett v. Spear*, 520 U.S. 154, 178 (1997). But the press release, which merely announces and summarizes the pharmacy guidance and certain other initiatives of HHS, does not determine any legal rights or obligations or represent the consummation of HHS’s decisionmaking process. The Court’s Motion to Dismiss Opinion did not hold otherwise. Although that opinion concluded that “the Pharmacy Guidance is reviewable as ‘final agency action.’” ECF No. 44, at 22,³ it did not hold that the press release itself was reviewable final agency action. Accordingly, defendants are not obligated to produce an administrative record for the press release.

³ Defendants have asked the Court to reconsider its conclusion that the Superseded Guidance is final agency action, Doc. 55 at 17–18, but in recognition of that conclusion, defendants have submitted administrative records for both the Superseded Guidance and the Revised Guidance.

November 17, 2023

Respectfully submitted,

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I certify that on November 17, 2023, I served the foregoing document via the Court's CM/ECF system upon plaintiffs via their counsel as follows:

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